

QUALITY MANUAL COMPLETENESS CHECKLIST FOR NEW APPLICANTS – 1 VAC 30-45

Please indicate by section number and/or page number, where the following elements are found in the Laboratory Quality Manual

1 VAC 30-45-610 A. The laboratory shall document its quality system in a quality manual. The quality manual shall reflect all quality assurance and quality control practices and programs used by the laboratory. The required elements of the quality system may be described in more than one document. The elements of a quality manual shall include but not be limited to:					
Mandatory Quality Elements	Laboratory Reference	INTERNAL USE ONLY			
		Document Compliant			Comments and Corrective Actions
		Y	N	N/A	
1 VAC 30-45-610 B 1. Title page, including document title, lab's name & address, telephone number of individual(s) responsible for lab, name of QA officer, laboratory facility(ies) covered by the quality manual, signed and dated concurrence of responsible official, lab manager, and QA officer, & effective date					
1 VAC 30-45-610 B 2. Table of contents					
1 VAC 30-45-610 B 3. Quality policy statement, including objectives of the quality system, and commitments to good laboratory practices					
1 VAC 30-45-610 B 4. Organization & management structure, organizational charts, relationship to parent organization					
1 VAC 30-45-610 B 5. Relationship between management, technical operations, support services & quality system					
1 VAC 30-45-610 B 8. Processes or procedures for establishing that personnel have adequate training and experience in the duties they are expected to carry out and are receiving any needed training SUBMIT AN ANALYST'S COMPLETE TRAINING RECORD, INCLUDING SUPPORTIVE DEMONSTRATION OF CAPABILITY DOCUMENTATION.					DATA REVIEW REQUIRED.
1 VAC 30-45-610 B 7. Job descriptions of key staff and reference to job descriptions of other staff					
1 VAC 30-45-610 B 9. Ethics policy statement developed by the laboratory. Processes and procedures for educating and training personnel in their ethical and legal responsibilities including the potential penalties for improper, unethical or illegal actions.					
1 VAC 30-45-610 B 11. Procedures to ensure that all records required by Chapter 45 are retained, as well as procedures for control and maintenance of documentation through a document control system					

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1 VAC 30-45-610 B 10. Procedures for reviewing new work & ascertaining appropriateness of facilities & resources prior to commencing new work					
1 VAC 30-45-610 B 12. Procedures for dealing with complaints					
1 VAC 30-45-610 B 16. Management arrangements for permitting departures from documented procedures or standard specifications					
1 VAC 30-45-610 B 15. Procedures followed for feedback & corrective action when testing discrepancies are detected or when departures to documented policies & procedures occur SUBMIT AN EXAMPLE OF DOCUMENTATION FOR CORRECTIVE ACTION TAKEN FOR A FAILED PT OR OTHER POLICY DEPARTURE. IF NONE, SUBMIT THE FORM TO BE USED FOR FUTURE CORRECTIVE ACTIONS.					DATA REVIEW REQUIRED.
1 VAC 30-45-610 B 13. Procedures for audits & management review					
1 VAC 30-45-610 B 6. The capabilities of the laboratory or scope of its operation					
1 VAC 30-45-610 B 19. List of all technology/methods under which the laboratory performs its certified testing SUBMIT TWO STANDARD OPERATING PROCEDURES FOR REQUESTED METHODS (unless only one method is requested).					DATA REVIEW REQUIRED.
1 VAC 30-45-610 B 20. Procedures for achieving traceability of measurements SUBMIT SAMPLES OF RECORDS TO BE USED FOR DOCUMENTATION OF TRACEABILITY SUCH AS FOR THE REAGENTS AND STANDARDS USED IN AN ANALYSIS.					DATA REVIEW REQUIRED.
1 VAC 30-45-610 B 17. Reference to major equipment, reference standards, facilities & services used in conducting tests					
1 VAC 30-45-610 B 18. Reference to procedures for calibration, verification and maintenance of equipment					
1 VAC 30-45-610 B 21. Procedures for receiving, handling, storing, and disposing of submitted samples SUBMIT AN EXAMPLE PAGE FROM THE LABORATORY'S SAMPLE RECEIVING LOG.					DATA REVIEW REQUIRED.
1 VAC 30-45-610 B 14. Reference to verification practices (e.g., proficiency testing, interlaboratory comparisons, use of reference materials & internal QC schemes) SUBMIT AN EXAMPLE OF THE LABORATORY'S CALIBRATION DATA AND ASSOCIATED QUALITY CONTROL FOR TWO ANALYSIS METHODS (or one if only one method is requested).					DATA REVIEW REQUIRED.
1 VAC 30-45-610 B 22. Reference to procedures for reporting analytical results					